Summary of GAO Findings

Most ADAPs Have Limitations on Coverage

"Of the 52 ADAPs [GAO] reviewed, 29 reported to HRSA that their programs had one or more program design limitations, which also contributed to coverage differences among ADAPs for grant year 2004. These included a limit on an individual's assets, copayment requirements, caps on program enrollment, or caps on expenditures per individual enrollee. Sixteen ADAPs reported that they have a limit on assets that enrollees are allowed to have, 9 reported having a copayment for drugs provided, 7 reported having a cap on the number of individuals enrolled, and 5 reported having a cap on amounts expended per enrollee for HIV/AIDS drugs. Eight ADAPs reported using more than one of these criteria." (pages 16 and 17)

ADAP Eligibility Varies

"An individual eligible for ADAP services in one state may not be eligible in another state." (page 11)

"Each ADAP determines a maximum income level, or income ceiling, as criterion for an individual's eligibility for enrollment. ADAPs report income ceilings for the 2004 grant year that ranged from 125 percent of the federal poverty level in North Carolina to 556 percent in Massachusetts. Also, of the 52 ADAPs, 16 reported that they have dollar limits on the assets that individuals enrolled in the program are allowed to have. Twelve ADAPs reported having caps on program enrollment or on amounts expended per individual for HIV/AIDS drugs." (page 11)

"Each ADAP has an income ceiling, which is the maximum income an individual can have and be eligible for the program. … Income ceilings reported to HRSA for the 2004 grant year ranged from the most restrictive at 125 percent of the federal poverty level, or $11,638, in North Carolina to the most generous at 556 percent, or $51,764, in Massachusetts." (page 14)

ADAP Treatment Coverage Varies

"ADAPs are not required to cover particular drugs or a minimum number of drugs. The Food and Drug Administration (FDA) has approved 27 HIV/AIDS drugs in four drug classes." (page 19)

"In fiscal year 2004, the number of drugs included in ADAPs' formularies ranged from 20 in Colorado to 1,000 in Massachusetts, New Hampshire, and New Jersey." (page 11)

ADAP Waiting Lists May Not Represent All Individuals Not Being Treated

"HRSA's HIV/AIDS Bureau does not have guidance on what conditions should trigger an ADAP to establish a waiting list. In fiscal year 2004, 14 ADAPs had waiting lists of individuals they determined were ADAP eligible but the programs were unable to serve." (page 28)

"The ADAPs with waiting lists may not represent all eligible individuals who are not being served. During fiscal year 2004, there were 14 ADAPs that reported having waiting lists for at least part of the year." (pages 7 and 8)

GAO did "not know whether any ADAP turned away individuals who would have been eligible without establishing a waiting list." (page 28)

ADAPs Are Paying Higher Prices for Drugs Than Necessary

"Under Section 340B of the Public Health Service Act, drug manufacturers provide discounts in certain outpatient drugs to covered entities; a 340B price, sometimes referred to as a 340B ceiling price, is established for each covered drug that entities purchase. ADAPs are allowed to purchase drugs through the Section 340B program and are required to submit quarterly HIV/AIDS drug pricing reports to HRSA that indicate what they paid for drugs." (page 3)

"An ADAP's participation in the 340B program is voluntary—they may choose, for example, to negotiate drug prices themselves with drug companies." (page 9)

"Some ADAPs reported prices to HRSA for some of the top HIV/AIDS drugs that were higher than the 340B program prices. Drug manufacturers that agree to participate in the 340B drug pricing program agree to sell HIV/AIDS drugs too 340B entities, including ADAPs that participate in the program, at prices no greater than the 340B prices." (page 12)

"All of the 25 ADAPs that used the 340B direct purchase option reported prices to HRSA that were higher than the 340B price for at least one of the top 10 drugs. … Of the 27 ADAPs that used the 340B rebate option to purchase drugs in 2003, all except 3 ADAPs reported paying drug prices that were higher than the 340B prices for many of the top 10 drugs. The prices that ADAPs using the drug rebate option report for the drugs they purchase may not reflect the rebates that they eventually receive and therefore may not be the final prices these ADAPs pay for the drugs." (page 12)

"Without the final ADAP rebate amount on a drug purchase, HRSA cannot determine whether the final drug prices paid were at or below the 340B price." (page 12)

"Three ADAPs reported prices that were more than then the 340B price for at least 8 of the 10 drugs—Delaware (10), Oklahoma (9), and Kentucky (8)." (page 32)

"Since ADAPs are not provided the 340B prices, they may be unknowingly paying more than the 340B price for a drug." (pages 32 and 33)

"The ADAPs' and the 340B prime vendors' negotiating position is disadvantaged because they rely on the drug manufacturers they negotiate with to tell them whether the negotiated prices are equal to or better than the 340B prices." (page 35)

"From 2000 to 2003, all available prices for the top 10 HIV/AIDS drugs increased under the 340B, FCP, and FSS, except for Norvir which had a decrease in its 340B prices. During the same period, all available drug prices decreased under the Medicaid program." (pages 40 and 41)

HRSA Does Not Routinely Check if ADAPs are Receiving Appropriate Prices

"All ADAPs submit quarterly HIV/AIDS drug pricing reports to the HIV/AIDS Bureau that indicate what they paid. The Bureau can request that OPA compare the ADAP price reports to the 340B price, but OPA cannot share its price comparisons with the Bureau due to the confidentiality of the 340B prices. If a state or territory does not comply with the grant conditions, HRSA can either restrict the use of its current grant funds or deny the state or territory future grant funds." (page 10)

"Although HRSA is responsible for monitoring whether ADAPs are complying with conditions of their grants, it does not routinely compare the drug prices ADAPs pay to 340B prices." (page 12)

"Based on its finding that HRSA did not conduct systematic monitoring of 340B prices, in December 2005, the HHS OIG recommended that HRSA develop monitoring mechanisms to compare the 340B prices to the prices paid by 340B entities, which include ADAPs. During the course of [GAO's] review, Bureau and OPA officials told [GAO] that they were discussing plans for OPA to begin making routine comparisons of the prices reported by the ADAPs to the 340B prices. As of April 2006, final decisions have not been made about when the comparisons will begin, how often they will be made during a year, or whether the results will be shared with the ADAPs. If the price comparisons do not include the rebates ADAPs receive and 340B prime vendor prices, the comparisons cannot indicate whether the prices all ADAPs paid for their drugs were at or below the 340B prices." (page 37)

GAO notes that routinely comparing the prices of drugs purchased by ADAPs to 340B prices "could also help HRSA to better monitor the final prices for the drugs and to gauge whether ADAPs are achieving maximum results with their grant funds." (page 42)

Medicaid Pays the Highest Prices for Some Common AIDS Drugs

"Medicaid is the largest source of federal funding for HIV/AIDS health care services. In fiscal year 2005, Medicaid provided an estimated $5.7 billion in HIV/AIDS health care assistance." (page 7)

"The Medicaid rebate program prices, available to state Medicaid programs, were the highest of all the drug pricing programs for 3 of the 7 drugs for which [GAO] had prices from all programs. The three drugs were Norvir, Sustiva, and Trizivir." (page 13)

Most ADAPs Receive Funds from Sources Other Than the Federal ADAP Base Grant

"In fiscal year 2004, 46 of 52 ADAPs [GAO] reviewed reported receiving additional funds from sources that included Severe Need grants, transfers from Title II base grants, transfers from Title I grants, contributions from state or territory, and other sources. Nineteen states received funding from three or more of the additional funding sources." (page 21)

"Nine ADAPs reported receiving Title I fund transfers from the EMAs in their states ranging from $65,250 in Nevada to about $6 million for New York. The total amount of Title I grantee transfers was about $10.9 million." (page 24)

"Thirty-five ADAPs reported receiving contributions from their respective jurisdiction's non-CARE Act funds ranging from about $8,000 in Ohio to about $64 million in California." (page 24)

"In June 2004, the President announced that $20 million would be used to provide HIV/AIDS drug assistance to over 1,700 individuals then on ADAP waiting lists in ten states." (page 30)

"Six ADAPs—Iowa, New Hampshire, New Mexico, Tennessee, Utah, and Wyoming—did not report receiving any additional funding." (page 25)

Many States Do Not Contribute Funds to ADAP or Do Not Apply for Additional Funding

States that did not contribute to ADAP include Delaware, Indiana, Iowa, Maryland, Michigan, New Hampshire, New Jersey, New Mexico, North Dakota, Rhode Island, South Dakota, Tennessee, Utah, and Wyoming. (pages 23and 23

"Three states whose ADAPs had waiting lists were eligible to receive Severe Need grants in fiscal year 2004, but did not apply." (page 30)

Some States with ADAP Waiting Lists Receive Funds from Other CARE Act Sources

Among the 14 ADAPs with waiting lists:

- 8 received funds from Severe Needs grants;
- 8 received transfers from Title II base grant funds;
- Only one—Colorado—received a Title I transfer;
- 9 received contributions from state funds.

(page 30)

Early Identification of HIV-infection is Necessary for Prevention

"Research suggests that most new HIV infections originate from HIV-infected persons not yet aware of their infection. This emphasizes the need to identify HIV-infected persons and link them with appropriate services as soon as possible." (page 49)

Prevention of Perinatal HIV Depends Upon Routine Testing

"According to CDC, the prevention of perinatal HIV transmission depends on routine testing of pregnant women for HIV and the use of antiretroviral drug treatment and obstetrical interventions." (page 45)

"Allowing pregnant women to 'opt out' of HIV testing is the approach to HIV testing that CDC recommends." (page 47)

"Connecticut and New York have enacted laws that require HIV testing of newborns." (page 47)

"Officials from Connecticut and New York told [GAO] that their mandatory newborn testing laws resulted in an increase in the number of pregnant women who were tested for HIV. A Connecticut official stated that the rate of HIV testing of pregnant women before the state's mandatory testing law passed was about 25 percent and since the law was enacted, the state's testing rate has increased to 90 percent or more. Similarly, New York officials told [GAO] that prenatal HIV testing has increased. Data on New York prenatal testing show that the prenatal HIV testing rate had increased from 64 percent in 1997 to 95 percent in 2003." (pages 47 and 48)

"Few states collect the data needed to determine statewide perinatal HIV transmission rates." (page 46)

Barriers Deter Partner Notification

GAO examined partner counseling and referral services (PCRS) in twelve states.

"In New York, North Carolina, and Texas, statutory or regulatory provisions require that public health officials or health departments notify partners, including spouses, of their possible expose to HIV. In California, Connecticut, Florida, Missouri, New York, Pennsylvania, and Washington, the provisions permit health care providers, public health officials, or health departments to notify partners, including spouses, of their possible exposure to HIV." (page 53)

"In the remaining two states—Massachusetts and Minnesota—public health officials or health department may notify partners only with the consent of the index case. Moreover, Massachusetts has an HIV-specific confidentiality provision that explicitly prohibits health care providers and facilities from disclosing an individual's name or HIV test results without the individual's written informed consent. Massachusetts officials said that they believe the number of partners notified is lower in states with strict confidentiality laws compared to states without strict laws." (page 54)

"In California where physicians are permitted to notify partners, a California official told [GAO] that the health department is trying to get physicians more involved in partner notification but said that generally physicians do not have the time or staff to conduct notifications." (pages 53 and 54)

"A California state official told [GAO] that because the state does not use name-based reporting of individuals diagnosed with HIV, the state is not able to track those who receive partner services and how many actually got tested." (page 55)

"New York officials [GAO] contacted said that the proportion of HIV index cases that do not provide partner identifying information is quite high. They do not know what percent of index cases refuse to divulge the information versus the health care provider's failure to ask or record the information. In 2003, New York City health care providers submitted 5,213 reports to the city's HIV Epidemiology Program that were completed on patients with a new diagnosis of HIV. Seventy-five percent of the reports did not list a partner of the newly diagnosed HIV-positive patient." (page 52)

"Pennsylvania Department of Health officials told [GAO] that in 2004, there were over 300 HIV-positive cases in the state, and that 89, or less than one third, used PCRS." (page 55)

<u>Nearly All Partners Notified and Counseled Seek Testing</u>

"Among partners who were located and notified, about 89 percent received counseling, and approximately 90 percent of partners who were counseled were counseled were then tested for HIV." (page 55)

How GAO Finds Are Addressed by S. 2339/H.R. 5009, The Coburn/Weldon Ryan White CARE Act Amendments of 2006

Eliminating Waiting Lists for Lifesaving AIDS Drug

GAO found that 14 ADAPs had waiting lists of eligible patients that the programs were unable to serve and that these ADAP waiting lists may not represent all eligible individuals who are not being served. S. 2339 seeks to ensure all those with HIV/AIDS have access to treatment. The bill, in fact, requires that 75 percent of all CARE Act funds be spent on primary medical care including treatment, to ensure that life saving treatment is the first priority of the program (Section 4). To specifically address ADAP shortfalls, S. 2339 authorizes annual increases of $70 million for ADAP (section 16) plus an amount up to 8 percent of the total ADAP budget would be authorized for ADAP supplemental grants targeted to states that need additional assistance providing AIDS medication (Section 5). Additionally, unspent CARE Act dollars, often tens of millions every year, would be recaptured and reallocated through the ADAP supplemental and up to $5 million in administrative funds would also be permitted to be directed into ADAP (Section 5).

Updating ADAP Formularies to Ensure Essential Drugs Are Included

According to GAO, ADAPs are not required to cover particular drugs or a minimum number of drugs. Therefore, patients in one state may not have access to the same medications as a patient in a nearby state. To ensure that all patients have access to those drugs that are truly necessary, S. 2339 requires HRSA to develop a recommended minimum standard drug formulary for AIDS treatment (Section 13). S. 2339 also authorizes states to expand formularies to include treatment for hepatitis B and hepatitis C (Section 9).

Ensuring CARE Programs Are Receiving Best Prices for Drugs

GAO found that many states may not be receiving the best prices on AIDS drugs possibly because HRSA does not routinely check to ensure that ADAPs are paying the proper prices. Therefore, ADAPs may not be achieving maximum results with their grant funds and patients may not be receiving the amount of care and treatment they otherwise could. S. 2339 requires HRSA to conduct routine analysis of prices ADAPs pay for AIDS drugs and requires that all CARE Act components coordinate drug purchases (Section 15).

Increasing Opportunities for Early Intervention Services

According to GAO, most new HIV infections originate from HIV-infected persons not yet aware of their infection." GAO concluded that "This emphasizes the need to identify HIV-infected persons and link them with appropriate services as soon as possible." According to GAO, some states still have legal or regulatory barriers that hinder confidential notification of the spouses and other partners of HIV index patients that they may be at risk for HIV infection and offered counseling and testing. This impedes efforts to break the chain of transmission and maximize treatment and prevention opportunities by made possible with early diagnosis and prompt treatment to those who are infected. S. 2339 provides routine testing of all clients at federal health facilities and patients in federal health programs to ensure greater opportunities for diagnosis at earlier stages of infection before a patient succumbs to AIDS related symptoms (Section 12). S. 2339 also directs CDC to distribute at least 1.5 million rapid tests annually (Section 12). Furthermore, S. 2339 requires states to eliminate legal barriers to confidential notification (Section 8), reauthorizes federal assistance for partner notification activities (Section 2), and sets up studies to evaluate the effectiveness of various forms of partner notification (Section 17).

Further Reducing Perinatal HIV Transmission

GAO found that the prevention of perinatal HIV transmission depends on routine testing of pregnant women and the use of antiretroviral drug treatment and that mandatory newborn testing laws resulted in an increase in the number of pregnant women who were tested for HIV. S. 2339 reauthorizes federal assistance for states to enact routine testing and counseling and treatment programs for pregnant women and newborns (Section 2) and also provides routine testing of pregnant women and newborns who utilize federal health facilities or insured under federal health programs (Section 12).